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33. An osteoimplant comprising a mechanically shaped composition of *elongate bone particles* selected from the group consisting of nondemineralized bone particles, demineralized bone particles, and combinations thereof, wherein the osteoimplant possesses a *void volume not greater than about 32%*.

The Examiner has rejected Claims 1, 3-7, 10-13 and 33-35 under 35 U.S.C. §102(b) for anticipation by Chen et al., U.S. Patent No. 5,707,962 ("Chen et al."). The Examiner has applied Chen et al. to these claims as follows:

... Chen et al. discloses the use of bone particles to make a sheet or membrane, col. 4, lines 44-47. Chen also discloses the source of materials can be allogenic or xenogenic and fillers can be added to the composition, col. 3, lines 4-6, 14-21. The bone particles can be demineralized, col. 4, lines 31-35. The collagen fleece contains elongate or fiber-like particles, see col. 7, lines 29-34. Chen also discloses the implant can have a "zone of impermeability" since the membrane or sheet is cross linked, col. 8, lines 5-9 and acts as a barrier, col. 9, lines 4-6. The Examiner asserts that the claimed physical properties (in this case a *void volume*) is present in the prior art material to some extent even though they are not explicitly recited. Chen does disclose a void volume (Col. 5, lines 4-6), but does not explicitly recite a percentage. Therefore, the Examiner hereby burdens the applicant to show that these properties (not greater than 32%) are not present in the prior art. It is noted that the void volume range includes 0%.

Applicants respectfully submit that the foregoing rejection is in error since Chen et al. fails to disclose, either expressly or inherently, either of the limitations of Claims 1 and 33 highlighted above.

Specifically, there is no disclosure anywhere in Chen et al. of *elongate bone derived elements*. The only bone-derived elements disclosed in Chen et al. are demineralized bone particles or demineralized bone powder. Nothing is said in Chen et al. regarding the shape of the demineralized bone "particles". The shape of the demineralized bone "powder" in Chen et al. is anything but elongate. Thus, in the Chen et al. examples illustrating a product produced from collagen and demineralized bone particles (Examples 1 and 2), a thick slurry of the combined materials is *blended in a Waring Blender*. Thus, even if elongate demineralized bone particles were originally present in the slurry (and, of course, Chen et al. is completely silent on this point), they would have been broken up or chopped into non-elongate particles before the final product, a sponge, could be formed.

In construing the Chen et al. disclosure, the Examiner makes indirect reference to the doctrine of inherency by stating that the claimed physical properties, in this case (void volume), is present in the prior art material "to some extent" even though they are not explicitly recited.

The doctrine of inherency holds that a property is necessarily present, given the nature of the disclosure, and is therefore disclosed even though the reference makes no express mention of the property. There is no such thing as inherency "to some extent". Either the "not greater than about 32 percent" void volume limitation of the claims is inherently disclosed in Chen et al. or it is not disclosed at all. Even assuming there is some void volume present in the Chen et al. product, it is unscientific to conclude that the void volume is necessarily not greater than about 32 percent.

Chen et al. does not relate the void volume of the disclosed implant, a sponge, with a particular quality of the implant. In the claims of the subject application, the recitation of less than 32% pore volume relates directly to the improved properties of this osteoimplant. Thus, in table 5 of the application, an implant prepared in accordance with the prior art (and containing a void volume considerably in excess of applicants' claimed maximum) had a much increased tendency to at least partially return to its original bent configuration than an implant prepared in accordance with the claimed invention. Applicants' implant for the most part exhibited no such tendency, or "memory". The advantage of a flexible membrane which exhibits little if any memory is that it will tend to remain conformed to the shape of the site where it is implanted, a desirable characteristic for many kinds of orthopedic surgical procedures.

Applicants' therefore respectfully submit that Chen et al. fails to anticipate any of Claims 1, 3-7, 10-13 and 33-35.

The Examiner has rejected Claims 2, 8 and 9 under 35 U.S.C. §103(a) for obviousness over Chen et al. The Examiner's rationale for the rejection is stated as follows:

...Chen is explained supra. However, Chen does not disclose a thickness of about 50-2000 microns and to mechanically shape the coherent mass of bone particles or composition to a specific 3-D architecture. Chen teaches that the implant can be used in various procedures, i.e., periodontal bone grafting (col. 6, lines 16-22). It would have been obvious to one of ordinary skill in the art to mechanically shape the implant into a 3-D component such that it would meet the individual's required physical specifications. It would have been obvious to one of ordinary skill in the art to vary the implant thickness to be about 50-2000 microns, since

applicant has not disclosed the thickness dimensions as an important feature or solves any stated problem or is for any particular purpose and it appears the thickness of Chen serves equally well.

Chen discloses the bone particles are demineralized at 90%, col. 7, line 39. However, Chen does not disclose bone particles that are fully demineralized (<8% mineral content). It would have been obvious to one of ordinary skill in the art to modify the composition of Chen et al. and fully demineralize the composition since applicant has not disclosed that fully demineralizing the bone particles as an important feature or solves any stated problem or is done for any particular purpose and it appears the implant would serve the same function with the partially demineralized bone particles.

The Examiner concedes that Chen et al. does *not* disclose a thickness of 50-2000 microns which is mechanically shaped in a coherent mass of elongate bone particles to a specific 3-D architecture, but that such a thickness and shaping would be obvious to one of ordinary skill in the art as it is utilized in various procedures. Applicants' again refer the Examiner to the experimental data presented in Table 5 of the specification where the almost total lack of memory of the claimed implant contrasts with the tendency of the prior art implant to return to its original shape. Chen et al. fails to suggest the structural parameters that make this property possible, i.e., applicants' use of elongate bone particles and providing less than about 32% average void volume.

In view of the foregoing, Claims 2, 8 and 9 are believed to define patentable invention over Chen et al.

Reconsideration and allowance of Claims 1-13 and 33-35 by the Examiner are once again respectfully requested.

Respectfully submitted,



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